ARTHRITIS & RHEUMATOLOGY
Vol. 67, No. 2, February 2015, pp 568–575
DOI 10.1002/art.38905

The Prevalence of Fibromyalgia in the General Population

A Comparison of the American College of Rheumatology 1990, 2010, and Modified 2010 Classification Criteria

Gareth T. Jones,[1] Fabiola Atzeni,[2] Marcus Beasley,[1] Elisa Flüß,[1] Piercarlo Sarzi-Puttini,[3] and Gary J. Macfarlane[1]

Objective. **The American College of Rheumatology (ACR) 1990 fibromyalgia classification criteria are based on the presence of widespread pain and tenderness. In 2010, new criteria were proposed that focused more on multiple symptoms, and these criteria were later modified to require only self report of symptoms. The current study aimed to determine the population prevalence of fibromyalgia and to compare differences in prevalence using the alternative criteria.**

Methods. **A cross-sectional survey was conducted. Questionnaires, including items on pain, symptoms, and rheumatologic diagnoses, were mailed to 4,600 adults in northeast Scotland. Participants who had chronic widespread pain or those who met the modified 2010 criteria, plus a subsample of other participants, were invited to attend a research clinic. Attendees completed an additional questionnaire and underwent a rheumatologic examination, and their signs and symptoms were classified according to the ACR 1990, 2010, and modified 2010 criteria. The prevalence of fibromyalgia according to each set of criteria was calculated, weighting back to the target population by age, sex, and area of residence.**

Results. **Of 1,604 questionnaire participants, 269 were invited to attend the research clinic, and 104 (39%) attended; 32 of these subjects (31%) met ≥1 set of fibromyalgia criteria. The prevalence of fibromyalgia according to the 1990, 2010, and modified 2010 criteria was 1.7% (95% confidence interval [95% CI] 0.7–2.8), 1.2% (95% CI 0.3–2.1), and 5.4% (95% CI 4.7–6.1), respectively. The ratio of females to males was 13.7:1, 4.8:1, and 2.3:1 of those meeting the respective criteria sets.**

Conclusion. **Fibromyalgia prevalence varies with the different sets of classification criteria applied. In particular, prevalence is higher and a greater proportion of men are identified with the modified 2010 criteria as compared to the criteria sets requiring clinician input. This has important implications for the use of the new criteria, both in research and in clinical practice.**

Fibromyalgia is one of the most common reasons for referring a patient to a rheumatologist (1), and while there are a number of estimates of the occurrence of fibromyalgia in rheumatology clinic populations, there are few studies of its prevalence in the general population. Data from a national health interview survey in Denmark estimated the prevalence to be <1% (2). Other investigators have reported a prevalence of 2.4% in Spain (3); and in North America, estimates vary from 2.0% to 3.3% (4,5). Fibromyalgia prevalence increases with age, reaching a peak around the seventh decade of life, and at every age it is more common in women than in men (4).

Supported by the University of Aberdeen Development Trust from charitable donations for research in the study of fibromyalgia.

[1]Gareth T. Jones, PhD, Marcus Beasley, MSc, Elisa Flüß, PhD, Gary J. Macfarlane, MD, PhD: University of Aberdeen, Aberdeen, UK; [2]Fabiola Atzeni, MD, PhD: University of Aberdeen, Aberdeen, UK, and L. Sacco University Hospital, Milan, Italy; [3]Piercarlo Sarzi-Puttini, MD: L. Sacco University Hospital, Milan, Italy.

Address correspondence to Gareth T. Jones, PhD, Epidemiology Group, Institute of Applied Health Sciences, University of Aberdeen, School of Medicine and Dentistry, Polwarth Building, Foresterhill, Aberdeen AB25 2ZD, UK. E-mail: gareth.jones@abdn.ac.uk.

Submitted for publication February 12, 2014; accepted in revised form October 2, 2014.

Table 1. American College of Rheumatology 1990 criteria for the classification of fibromyalgia*

1. History of widespread pain
   Definition: Pain is considered widespread when all of the following are present: pain in the left side of the body, pain in the right side of the body, pain above the waist, and pain below the waist. In addition, axial skeletal pain (cervical spine or anterior chest or thoracic spine or low back) must be present. In this definition, shoulder and buttock pain is considered as pain for each involved side. "Low back" pain is considered lower segment pain.
2. Pain in ≥11 of 18 tender point sites on digital palpation
   Definition: Pain, on digital palpation, must be present in at least 11 of the following 18 tender point sites:

Occiput:	Bilateral, at the suboccipital muscle insertions
Lower cervical:	Bilateral, at the anterior aspects of the intertransverse spaces at C5–C7
Trapezius:	Bilateral, at the midpoint of the upper border
Supraspinatus:	Bilateral, at the origins, above the scapula spine near the medial border
Second rib:	Bilateral, at the second costochondral junctions, just lateral to the junctions on the upper surfaces
Lateral epicondyle:	Bilateral, 2 cm distal to the epicondyle
Gluteal:	Bilateral, in the upper outer quadrants of the buttocks in the anterior fold of the muscle
Greater trochanter:	Bilateral, posterior to the trochanteric prominence
Knee:	Bilateral, at the medial fat pad proximal to the joint line

   Digital palpation should be performed with an approximate force of 4 kg. For a tender point to be considered "positive," the subject must state that the palpation was painful."Tender" is not to be considered "painful."

* For classification purposes, a patient will be said to have fibromyalgia if both criteria are satisfied. Widespread pain must have been present for at least 3 months. The presence of a second clinical disorder does not exclude the diagnosis of fibromyalgia. Reformatted from ref. 6.

Table 2. American College of Rheumatology 2010 preliminary diagnostic criteria for fibromyalgia*

A patient satisfies the diagnostic criteria for fibromyalgia if the following 3 conditions are met:
1. A Widespread Pain Index (WPI) of ≥7 and a Symptom Severity (SS) Scale score of ≥5, or a WPI between 3–6 and an SS scale score of ≥9
2. Symptoms have been present at a similar level for at least 3 months
3. The patient does not have a disorder that would otherwise explain the pain

Ascertainment

WPI: Note the number of areas in which the patient has had pain over the previous week. In how many areas has the patient had pain? Score will be between 0 and 19.†

Shoulder girdle (left and right)	Jaw (left and right)
Upper arm (left and right)	Chest
Lower arm (left and right)	Abdomen
Hip (buttock, trochanter) (left and right)	Upper back
Upper leg (left and right)	Lower back
Lower leg (left and right)	Neck

SS: For each of the symptoms of fatigue, waking unrefreshed, and cognitive symptoms, indicate the level of severity over the previous week, using the following scale:
- 0 = no problem
- 1 = slight or mild problems, generally mild or intermittent
- 2 = moderate, considerable problems, often present and/or at a moderate level
- 3 = severe: pervasive, continuous, life-disturbing problems

Considering somatic symptoms in general, indicate whether the patient has the following:‡
- 0 = no symptoms
- 1 = few symptoms
- 2 = a moderate number of symptoms
- 3 = a great deal of symptoms

The SS scale score is the sum of the severity of the 3 symptoms (fatigue, waking unrefreshed, and cognitive symptoms) plus the extent (severity) of somatic symptoms in general. The final score is between 0 and 12.

* Reformatted from ref. 7.
† Areas indicated as left and right should be scored separately.
‡ Somatic symptoms that might be considered are as follows: muscle pain, irritable bowel syndrome, fatigue/tiredness, thinking or remembering problems, muscle weakness, headache, pain/cramps in the abdomen, numbness/tingling, dizziness, insomnia, depression, constipation, pain in the upper abdomen, nausea, nervousness, chest pain, blurred vision, fever, diarrhea, dry mouth, itching, wheezing, Raynaud's phenomenon, hives/welts, ringing in the ears, vomiting, heartburn, oral ulcers, loss of/change in taste, seizures, dry eyes, shortness of breath, loss of appetite, rash, sun sensitivity, difficulties with hearing, easy bruising, hair loss, frequent urination, painful urination, and bladder spasms.

Table 3. Modification of the American College of Rheumatology 2010 preliminary diagnostic criteria for fibromyalgia*

Criteria

A patient satisfies the modified 2010 fibromyalgia diagnostic criteria if the following 3 conditions are met:

1. A Widespread Pain Index (WPI) of ≥7 and a Symptom Severity (SS) Scale score of ≥5, or a WPI between 3–6 and an SS Scale score of ≥9
2. Symptoms have been present at a similar level for at least 3 months
3. The patient does not have a disorder that would otherwise sufficiently explain the pain

Ascertainment

WPI: Note the number of areas in which the patient has had pain over the previous week. In how many areas has the patient had pain? Score will be between 0 and 19.†

Shoulder girdle (left and right)	Jaw (left and right)
Upper arm (left and right)	Chest
Lower arm (left and right)	Abdomen
Hip (buttock, trochanter) (left and right)	Upper back
Upper leg (left and right)	Lower back
Lower leg (left and right)	Neck

SS: For each of the symptoms of fatigue, waking unrefreshed, and cognitive symptoms, indicate the level of severity over the previous week, using the following scale:

0 = no problem
1 = slight or mild problems; generally mild or intermittent
2 = moderate; considerable problems; often present and/or at a moderate level
3 = severe: pervasive, continuous, life-disturbing problems

The SS Scale score is the sum of the severity of the 3 symptoms above plus the sum of the number of the following symptoms occurring during the previous 6 months: headaches, pain or cramps in the lower abdomen, and depression (0–3). The final score is between 0 and 12.

* Reformatted, with permission, from ref. 8.
† Areas indicated as left and right should be scored separately.

All of the above-cited studies used the American College of Rheumatology (ACR) 1990 criteria for the classification of fibromyalgia (6), comprising 1) a history of chronic widespread pain (pain present for at least 3 months and affecting the left and right sides of the body, above and below the waist, and in the axial skeleton) plus 2) pain on digital palpation in ≥11 of 18 specific sites (Table 1).

In 2010, new classification criteria for fibromyalgia were proposed (the "ACR preliminary diagnostic criteria" [7]), which differed from the 1990 criteria in 2 main respects: first, the 2010 criteria operationalized the measurement of chronic widespread pain, and second—and more fundamentally—they did away with the requirement for a tender point examination in favor of an assessment of fatigue, waking unrefreshed, cognitive symptoms, and somatic symptoms in general. Under these new criteria, a patient would be classified as having fibromyalgia if a clinician determined that they had 1) high levels of pain plus moderate levels of symptoms or moderate levels of pain plus high levels of symptoms, 2) symptoms present at a similar level for ≥3 months, and 3) no disorder that would otherwise explain the pain (Table 2). These criteria have not been formally adopted and are only "approved by the ACR Board of Directors as provisional" (7).

Then, in 2011, a modified version of the 2010 criteria was proposed that relied on self-reported pain and a simplified self-reported version of somatic symptoms (8) for use in clinical and epidemiologic studies. These preliminary research criteria are referred to hereinafter as the modified 2010 criteria (Table 3).

The prevalence of fibromyalgia according to the ACR modified 2010 criteria was assessed in a large population survey in Germany (9). Fifty-two of 2,445 participants were found to have fibromyalgia, yielding a prevalence of 2.1%. Given the reliance on self report and the absence of clinical judgment, one might expect an elevated estimate of prevalence. However, the authors concluded that the modified 2010 criteria did not result in high levels of fibromyalgia. It is not known, however, what the prevalence of fibromyalgia in this population would have been if the 1990 classification criteria had been used and, therefore, to what extent this is a valid conclusion.

To the best of our knowledge, there have been no published studies of fibromyalgia comparing the ACR 1990, 2010 (preliminary diagnostic), and modified 2010 (preliminary research) classification criteria for fibromyalgia in the general population. Thus, the aim of the current study was, first, to determine the prevalence of fibromyalgia in the general population, second, to com-

pare the prevalence estimates obtained using the established (ACR 1990) and the 2 proposed (ACR 2010 and ACR modified 2010) classification criteria sets, and third, to determine the main influences of any differences in identified cases when using the alternative criteria sets.

SUBJECTS AND METHODS

Study overview. A 2-stage population-based prevalence study was conducted during the last quarter of 2012 and the first quarter of 2013. This consisted of a cross-sectional postal questionnaire survey, followed by a clinical examination of a subset of survey participants.

Population survey. In the UK, the majority of healthcare is provided by the National Health Service (NHS); it is estimated that in 2009, only 3% of all general practice consultations were undertaken by private primary care practitioners (10). Thus, the NHS general practice lists provide a convenient population-based sampling frame for epidemiologic research. A sample of 4,600 individuals ≥25 years of age was randomly selected from the NHS register in Grampian, northeast Scotland, a region with a single city (Aberdeen) and a mixture of suburban and rural areas, with a mid-year 2010 population estimate of ~340,000 persons ≥25 years of age.

Selected individuals were sent an advance letter, indicating that they had been chosen for the study. This was followed 1 week later by the survey pack. The pack consisted of an invitation letter, an information sheet, the questionnaire, and a prepaid reply envelope. Two weeks later, a duplicate pack was sent to nonrespondents. Participants were asked the following question, "Thinking back over the past four weeks, have you had any aches or pains that have lasted for one day or longer?" Those answering "yes" were directed to shade the location of these pains on 4-view blank body manikin drawings and were asked whether they had experienced these pains for ≥3 months. They were also asked whether they had experienced pain or tenderness over the past 7 days in each of the areas listed in the Widespread Pain Index of the ACR modified 2010 fibromyalgia criteria, plus they were asked the questions that comprise the Symptom Severity Scale of the same criteria set (Table 3). They were also asked to report whether they had ever been told by a healthcare provider that they had one or more of the following: osteoarthritis (confirmed by radiography), rheumatoid arthritis, osteoporosis, lupus, scleroderma, ankylosing spondylitis, gout, or fibromyalgia.

Clinical examination. Participants who had a positive result on the screening questionnaire were those who reported 1) chronic widespread pain as per the ACR 1990 criteria and/or 2) fibromyalgia according to the ACR modified 2010 criteria.

In order to determine what proportion met the various criteria for fibromyalgia, these individuals were invited to attend the University of Aberdeen Clinical Research Facility for further examination. It was also important, however, to establish whether any participants who screened negative were deemed to have fibromyalgia on subsequent examination. Therefore, a subsample of participants who reported 1) pain that did not meet the above definition or 2) no pain was also invited to attend.

In the clinic, participants completed a second questionnaire and underwent a clinical examination by a single examiner (FA, a consultant rheumatologist). This included a full clinical history and tender point examination, as per the ACR 1990 criteria for fibromyalgia.

Prevalence of fibromyalgia. The numbers of fibromyalgia cases were determined as follows. For the ACR 1990 criteria, data were derived from the clinic questionnaire and tender point examination. For the ACR 2010 criteria, data were derived from the clinic questionnaire and clinical history/examination. For the ACR modified 2010 criteria, data were derived from the postal questionnaire.

The prevalence of fibromyalgia was then calculated, weighting the results to the target population by the inverse of the sampling fraction, with respect to age, sex, and area of residence (urban or rural).

Ethics approval. The study was approved by the North of Scotland Research Ethics Committee (REC reference no. 12/NS/0079).

RESULTS

Of 4,600 questionnaires distributed, 183 were considered not to have been received by the invited participant (for example, due to the letter being returned marked as deceased or as no longer resident at the given address), and 1,604 (36.3%) of the remaining 4,417 eligible invitees returned a completed questionnaire. The median age of the respondents was 55 years (interquartile range [IQR] 44–65 years), 55% were female, and the median time from sending the questionnaire to receiving a response was 6 days (IQR 3–16 days).

Of the questionnaire respondents, 269 were invited to attend the research clinic for a clinical examination; 104 of them (39%) attended, and 32 of those (31%) were found to meet at least 1 set of criteria for fibromyalgia: 11 participants met the ACR 1990 criteria, 7 met the ACR 2010 criteria, and 27 met the ACR modified 2010 criteria. The overlap between different sets of classification criteria was modest (Figure 1). In total, only 4 participants (12.5%) met all 3 criteria sets, and only 9 (28%) met >1 set.

The prevalence of fibromyalgia, as ascertained by the ACR 1990, 2010, and modified 2010 criteria, which was weighted back to the characteristics of the target population, was 1.7% (95% CI 0.7–2.8), 1.2% (95% CI 0.3–2.1), and 5.4% (95% CI 4.7–6.1), respectively. Compared to the ACR 1990 criteria, which was used as the gold standard, the ACR 2010 criteria had a sensitivity of

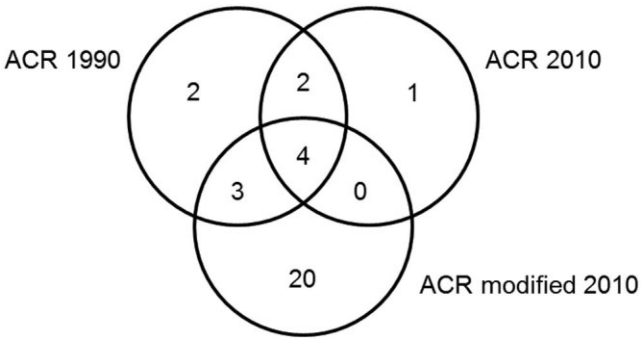

Figure 1. Overlap among the 3 different case definitions of fibromyalgia: the American College of Rheumatology (ACR) 1990 criteria, the ACR 2010 criteria, and the ACR modified 2010 criteria. Of the respondents to a mailed questionnaire who subsequently attended the research clinic and underwent examination, 11 met the 1990 criteria, 7 met the 2010 criteria, and 27 met the modified 2010 criteria. Only 4 participants met all 3 criteria sets, and only 9 met more than 1 set.

55% and a specificity of 99%; in contrast, these values for the modified 2010 criteria were 64% and 78%, respectively.

Patients meeting the ACR 1990 criteria were predominantly female, with a female-to-male ratio of 13.7:1. The ratio was lower in those meeting the ACR 2010 criteria (4.8:1), and lower still among those meeting the ACR modified 2010 criteria (2.3:1) (Table 4). There were also differences in the proportion of participants who reported prior rheumatologic diagnoses on their questionnaires (Table 4). This varied from more than half of those meeting the ACR 1990 criteria, to just over one-quarter of those meeting the ACR 2010 criteria. It should be noted, however, that these figures represent patient-reported diagnoses, which are completely independent of whether the examiner thought that the patient had "a disorder that would otherwise explain the pain."

Table 4. Prevalence of fibromyalgia, according to the ACR criteria set used*

ACR criteria set	Prevalence (95% CI)	Female-to-male ratio	% with rheumatologic diagnoses†
1990 criteria	1.7 (0.7–2.8)	13.7	55
2010 criteria	1.2 (0.3–2.1)	4.8	28
Modified 2010 criteria	5.4 (4.7–6.1)	2.3	45

* ACR = American College of Rheumatology; 95% CI = 95% confidence interval.
† Proportion of respondents who had a positive response to the question "Have you ever been told by a healthcare provider that you have any of the following diseases: osteoarthritis, rheumatoid arthritis, osteoporosis, lupus, scleroderma, ankylosing spondylitis, gout, or fibromyalgia?"

Table 5. Proportion of participants who met each case definition in the ACR modified 2010 criteria, stratified according to the ACR (non-modified) 2010 criteria*

ACR modified 2010 criteria case definition	ACR 2010 criteria: No. (%) positive (n = 4)	ACR 2010 criteria: No. (%) negative (n = 23)
Widespread Pain Index ≥7 plus Symptom Severity Scale score ≥5	4 (100)	16 (70)
Widespread Pain Index 3–6 plus Symptom Severity Scale score ≥9	0	7 (30)

* ACR = American College of Rheumatology.

This element of the ACR 2010 criteria (i.e., the exclusion of patients considered to have an underlying disorder, which is responsible for their pain) may explain both the low prevalence (1.2%), and the comparatively low proportion of cases reporting prior diagnoses. However, even without this exclusion, the prevalence was still considerably lower (2.6%) than that ascertained using the ACR modified 2010 criteria.

All participants who fulfilled both the ACR 2010 and modified 2010 criteria met the latter criteria set by reporting a high score on the Widespread Pain Index, rather than the Symptom Severity Scale (Table 5). In contrast, among the group who met only self-reported criteria, approximately one-third satisfied the case definition as a result of high levels of symptoms plus only moderate levels of pain (Table 5).

DISCUSSION

We have demonstrated that the prevalence of fibromyalgia varies more than 4-fold with the application of different ACR fibromyalgia classification criteria sets, the lowest estimate being with the 2010 criteria and the highest with the modified 2010 criteria. Further, we have shown that there are fundamental differences in the populations identified, in terms of sex ratio and preexisting comorbid rheumatologic conditions.

There are a number of methodologic issues to consider in the interpretation of these findings. First, the response rate in the initial survey was modest (36%). Questionnaire survey response rates have been falling over time (11), and a response of 30–40% is not uncommon. Compared to those who did not respond,

questionnaire respondents in the current study were significantly more likely to be female and were older. Also, only 39% of the 269 participants invited to attend the research clinic actually did so. Attenders were more likely to be male, older, and more likely to live in urban areas than those who were invited but did not attend. However, because the initial sampling frame was from the NHS register, information about age and sex was available not only on the questionnaire respondents, but also on all persons invited to participate in the initial survey. Thus, to counteract the effects of potential selection (nonparticipation) bias, the prevalence estimates were weighted back to the age and sex distribution of the target population and on the proportion living in urban/rural areas.

One limitation of the current study is that generalizations are made about the prevalence of fibromyalgia based, in some groups, on very small samples. For example, for men ≤50 years of age, there were no cases of fibromyalgia identified using either the ACR 1990 or the ACR 2010 criteria. Accordingly, the weighting process will assume that there are no cases at all in this particular population stratum. While this is probably unlikely, it is known that this is a group that has a particularly low risk of fibromyalgia (4), and so this finding is not unexpected.

Another limitation of the current study was the use of a single clinician (a consultant rheumatologist) for the clinical examination and case history. The clinical consultation is inherently a subjective experience, and it is possible that a different examiner might have come to a different conclusion regarding the tender points (ACR 1990 criteria) and/or "a disorder that would otherwise explain the pain" (ACR 2010 criteria). However, the use of a single clinician not only more closely resembles routine clinical practice, but in the context of a research study, it also has the desirable effect of reducing any between-participant variation. Further, the prevalence of fibromyalgia in the current study (1.7%, as ascertained using the ACR 1990 criteria) is exactly in the range one might expect based on other earlier studies in Europe and North America (2–5). Our sample size precludes a robust examination of differences in prevalence by various demographic characteristics, but it is worthy of note that cases, as would be expected, were more likely to be older females than younger males.

The specificity of the ACR 2010 criteria, as compared to the ACR 1990 criteria as a gold standard, was near-perfect. Of the 93 participants identified as not having fibromyalgia according to the 1990 criteria, 92 were correctly identified by the 2010 criteria. However, the sensitivity of the 2010 criteria was modest; just over half of the 1990 fibromyalgia cases were correctly identified by those criteria. The modified 2010 criteria, while exhibiting improved sensitivity (more participants positive for fibromyalgia according to the 1990 criteria were correctly identified), suffered from a decrease in specificity (fewer participants negative for fibromyalgia according to the 1990 criteria were correctly identified).

Other investigators have examined the sensitivity and specificity of the modified 2010 criteria in clinical populations. Bennett et al (12) found a specificity of 67% in patients with non-fibromyalgia chronic pain (i.e., 33% of people with other chronic pain conditions were incorrectly classified as having fibromyalgia with the new criteria). Similar to the current study (specificity of 78%), this is perhaps not surprising and is probably a function of the willingness of participants to self-report symptoms that, on physical examination by a clinician, were not considered eligible for inclusion. This is reflected in the fact that none of the participants who met both the 2010 (clinician-determined) and the modified 2010 (self-report) criteria sets did so as a result of a high symptoms score: all had a Widespread Pain Index of ≥7 and a Symptom Severity Scale score of ≥5, whereas nearly one-third of the participants who met the self-report criteria alone had a Widespread Pain Index of 3–6 plus a Symptom Severity Scale score of ≥9. However, the numbers in the former group were very small, and further validation of these findings in another study is warranted.

The other clear difference between the ACR 2010 and the modified 2010 criteria, other than being physician-completed versus patient-completed, is the fourth part of the Symptom Severity Scale. In the former, the physician is asked to rate somatic symptoms in general from 0 (no symptoms) to 3 (a great deal of symptoms), and more than 40 symptoms are listed that might be considered. Whereas, in the modified 2010 criteria, the same score, 0–3, is based on the patient's report of the total number of the following 3 symptoms that were present during the previous 6 months: headaches, pain or cramps in the lower abdomen, and depression. Agreement between the 2 methods was very poor ($\kappa = 0.09$). Participants were much more likely to report symptoms (27% reported none; 18% reported all 3) than was reflected in the physician's assessment of somatic symptoms generally (66% scored 0; 5% scored 3). This suggests that the former is not a good proxy for

the latter and explains (at least in part) the increased prevalence observed with the modified 2010 criteria.

Although the modified 2010 criteria have been used in several studies (9,13–16), this was almost exclusively in clinical populations, and we believe that the current study is the first to attempt to implement the new criteria by a group that is completely independent of the original author group. We found considerable difficulty operationalizing ACR 2010 criteria for fibromyalgia. To satisfy these criteria, a patient must meet several conditions: first, a certain pattern of pain and somatic symptoms must be present, and second, it is a requirement that "symptoms have been present at a similar level for at least 3 months." However, it is not clear from the proposed 2010 criteria (Table 2) whether this relates solely to the symptoms encompassed by the Symptom Severity Scale or whether it also includes pain. In addition, it is a requirement that the "patient does not have a disorder that would otherwise explain the pain," but similarly, it is not clear whether this relates solely to the Widespread Pain Index or whether it also includes some of the (painful) somatic symptoms.

These are subtle but crucial points, and it is likely that different observers might come to different conclusions about these criteria, even in the same patient. In the current study, we adopted an inclusive approach and interpreted "symptoms" to mean "symptoms and/or pain" and interpreted "pain" to mean "pain and/or other symptoms." Therefore, if any bias has been introduced, it will have served to overestimate the number of participants with symptoms (or pain) present at a similar level for at least 3 months, to overestimate the number of participants with a disorder that would otherwise explain the pain (or symptoms), and thus, to underestimate the prevalence of fibromyalgia according to the ACR 2010 criteria.

There was also difficulty operationalizing the modified 2010 criteria (Table 3). First, they suffer from the same interpretational problems as the ACR 2010 criteria, as described above. But more importantly, most patients are not sufficiently qualified to determine whether they have a disorder that would otherwise explain the pain (and/or symptoms). In the current study, although we asked participants to report whether they had ever been diagnosed as having 1 or more of a number of rheumatologic conditions, we excluded this condition when we determined the prevalence according to this criteria set. This will have served to overestimate the prevalence of fibromyalgia when using this definition. This is a concern because these criteria gave the highest prevalence estimates. However, were we to apply this condition (i.e., were we to exclude patients who had previously been diagnosed as having a rheumatologic condition), the prevalence drops by 44% (from 5.4% to 3.0%). We should stress, however, that on the questionnaire, participants were simply asked whether or not they had ever received such a diagnosis, and not whether they thought it explained their pain. Separately, and blindly with regard to the questionnaire data, the rheumatologist who examined the participants came to her own decision about the presence/absence of a condition, rheumatologic or otherwise, that might explain the pain and symptoms. It was this latter assessment that was used in the application of the ACR 2010 criteria.

The ACR 2010 and modified 2010 criteria reflect a conceptual change in the thinking about fibromyalgia—or at least in the classification of fibromyalgia—from predominantly a pain syndrome to a multisymptom syndrome. This paradigm shift may or may not be appropriate. There is a certain circularity in classification criteria being developed by clinicians and then being validated against "clinically diagnosed" patients (typically, the patients of the same clinicians). However, using the 2010 criteria, we have shown that 45% of patients previously classified as having fibromyalgia would now not be classified as such. This may have important implications for treatment, disability benefits, and health insurance.

The modified 2010 criteria also reflect a change from physician-derived classification criteria that are recommended for use in the clinic to criteria based on self-report that can be captured in large-scale epidemiologic surveys. However, the performance of these criteria when compared to the ACR 2010 criteria is not satisfactory, with a sensitivity of 57% and a specificity of 76%.

The current study is the first to compare all 3 sets of classification criteria in a general population sample, and our findings do not support previous claims that the modified 2010 criteria do not result in inflated prevalence estimates (9). Furthermore, we have demonstrated that the new set of criteria defines a demonstrably different patient group, as compared to that defined by the 1990 criteria (which they may replace). For example, the modified 2010 criteria set not only identifies a greater proportion of men, but also appears to be more influenced by somatic symptoms than by pain. Most importantly, operationalization of any new criteria must be clear and unambiguous, as well as immediately implementable. This is not currently the case. Both the

ACR 2010 criteria and the ACR modified 2010 criteria are currently considered "preliminary," and we strongly recommend that the ACR consider these important issues in deciding whether to confirm these proposed criteria for use in future clinical practice and/or research.

ACKNOWLEDGMENTS

We would like to thank Professor Sir Lewis Ritchie (Director of Public Health, NHS Grampian), who facilitated the use of NHS Grampian primary care records for sampling, John Lemon for assistance in questionnaire design, Professor Christine Bond for oversight of the initial population survey, and Sima Lionikaite, Maxx Livingstone, Georgia Mannion, Matthew Macfarlane, Rory Macfarlane, Giles O'Donovan, and Hazel Riley for assistance with data entry.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. Dr. Jones had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Jones, Atzeni, Beasley, Flüß, Sarzi-Puttini, Macfarlane.

Acquisition of data. Atzeni, Beasley, Flüß.

Analysis and interpretation of data. Jones, Atzeni, Beasley, Sarzi-Puttini, Macfarlane.

REFERENCES

1. White KP, Speechley M, Harth M, Ostbye T. Fibromyalgia in rheumatology practice: a survey of Canadian rheumatologists. J Rheumatol 1995;22:722–6.
2. Prescott E, Kjoller M, Jacobsen S, Bulow PM, Danneskiold-Samsoe B, Kamper-Jorgensen F. Fibromyalgia in the adult Danish population. I. A prevalence study. Scand J Rheumatol 1993;22:233–7.
3. Carmona L, Ballina J, Gabriel R, Laffon A. The burden of musculoskeletal diseases in the general population of Spain: results from a national survey. Ann Rheum Dis 2001;60:1040–5.
4. Wolfe F, Ross K, Anderson J, Russell IJ, Hebert L. The prevalence and characteristics of fibromyalgia in the general population. Arthritis Rheum 1995;38:19–28.
5. White KP, Speechley M, Harth M, Ostbye T. The London Fibromyalgia Epidemiology Study: the prevalence of fibromyalgia syndrome in London, Ontario. J Rheumatol 1999;26:1570–6.
6. Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier C, Goldenberg DL, et al. The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: report of the Multicenter Criteria Committee. Arthritis Rheum 1990;33:160–72.
7. Wolfe F, Clauw DJ, FitzCharles MA, Goldenberg DL, Katz RS, Mease P, et al. The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. Arthritis Care Res (Hoboken) 2010;62:600–10.
8. Wolfe F, Clauw DJ, FitzCharles MA, Goldenberg DL, Hauser W, Katz RS, et al. Fibromyalgia criteria and severity scales for clinical and epidemiological studies: a modification of the ACR preliminary diagnostic criteria for fibromyalgia. J Rheumatol 2011;38:1113–22.
9. Wolfe F, Brahler E, Hinz A, Hauser W. Fibromyalgia prevalence, somatic symptom reporting, and the dimensionality of polysymptomatic distress: results from a survey of the general population. Arthritis Care Res (Hoboken) 2013;65:777–85.
10. GHK Consulting Ltd in association with ICM Research. Programme of research exploring issues of private healthcare among general practitioners and medical consultants: population overview report for the Office of Fair Trading. London: GHK Consulting Ltd.; August 2011.
11. Morton LM, Cahill J, Hartge P. Reporting participation in epidemiologic studies: a survey of practice. Am J Epidemiol 2006;163:197–203.
12. Bennett RM, Friend R, Marcus D, Bernstein C, Han BK, Yachoui R, et al. Criteria for the diagnosis of fibromyalgia: validation of the modified 2010 preliminary American College of Rheumatology criteria and the development of alternative criteria. Arthritis Care Res (Hoboken) 2014;66:1364–73.
13. Hauser W, Jung E, Erbsloh-Moller B, Gesmann M, Kuhn-Becker H, Petermann F, et al. Validation of the Fibromyalgia Survey Questionnaire within a cross-sectional survey. PLoS One 2012;7:e37504.
14. FitzCharles MA, Ste-Marie PA, Panopalis P, Menard H, Shir Y, Wolfe F. The 2010 American College of Rheumatology Fibromyalgia Survey Diagnostic Criteria and Symptom Severity Scale is a valid and reliable tool in a French speaking fibromyalgia cohort. BMC Musculoskelet Disord 2012;13:179.
15. Usui C, Hatta K, Aratani S, Yagishita N, Nishioka K, Kanazawa T, et al. The Japanese version of the modified ACR preliminary diagnostic criteria for fibromyalgia and the Fibromyalgia Symptom Scale: reliability and validity. Mod Rheumatol 2013;23:846–50.
16. Ferrari R, Russell AS. A questionnaire using the modified 2010 American College of Rheumatology criteria for fibromyalgia: specificity and sensitivity in clinical practice. J Rheumatol 2013;40:1590–5.